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APPLICATION NO. FILING DATE		ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/939,656 08/28/2001		08/28/2001	Arthur E. Uber III	P 265228 VI/98-013.FWC.C.		
21140	7590	04/29/2004		EXAMINER		
GREGOR	Y L BRA	DLEY	DESANTO, MATTHEW F			
MEDRAD	INC					
ONE MED	RAD DRIV	√E	ART UNIT	PAPER NUMBER		
INDIANO	LA, PA 1	5051	3763	3763		

DATE MAILED: 04/29/2004

19

Please find below and/or attached an Office communication concerning this application or proceeding.

	1	Applicati	on No.	Applicant(s)					
		09/939,68	56	UBER, ARTHUR E.					
Office	Action Summary	Examine	,	Art Unit					
		Matthew F	DeSanto	3763					
The MAIL Period for Reply	ING DATE of this communicat	tion appears on the	cover sheet with the c	correspondence addr	9SS				
THE MAILING D  - Extensions of time mafter SIX (6) MONTH  - If the period for reply - If NO period for reply - Failure to reply within Any reply received by	STATUTORY PERIOD FOR ATE OF THIS COMMUNICA way be available under the provisions of 3 its from the mailing date of this communic specified above is less than thirty (30) day its specified above, the maximum statuto in the set or extended period for reply will, by the Office later than three months after the djustment. See 37 CFR 1.704(b).	TION. 7 CFR 1.136(a). In no evention. ays, a reply within the stat by period will apply and with state by statute, cause the app	ent, however, may a reply be tir utory minimum of thirty (30) day ill expire SIX (6) MONTHS from lication to become ABANDONE	nely filed  s will be considered timely. the mailing date of this come (D) (35 U.S.C.§ 133).	munication.				
Status									
1)⊠ Responsiv	e to communication(s) filed o	n 05 February 20	04.						
· ·									
3) Since this	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposition of Clair	ms								
4a) Of the 5) ☐ Claim(s) _ 6) ☑ Claim(s) <u>1</u> 7) ☐ Claim(s) _	3-18 and 63-91 is/are pendin above claim(s) is/are v is/are allowed.  3-18 and 63-91 is/are rejecte is/are objected to are subject to restriction	withdrawn from co	nsideration.						
Application Papers									
9) The specifi	cation is objected to by the E	xaminer.							
10)□ The drawin	☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.								
Applicant m	ay not request that any objection	n to the drawing(s) b	e held in abeyance. Se	e 37 CFR 1.85(a).					
	nt drawing sheet(s) including the r declaration is objected to by	•	• · · ·	<u>-</u>	• • •				
Priority under 35 U	.S.C. § 119								
a)	gment is made of a claim for Some * c) None of: ified copies of the priority docified copies of the priority docified copies of the priority docies of the certified copies of	cuments have bee cuments have bee he priority docume Bureau (PCT Rul	en received. en received in Applicati ents have been receive e 17.2(a)).	ion No ed in this National St	age				
Attachment(s)  1) X Notice of Reference			4) Interview Summary						
	son's Patent Drawing Review (PTO- ure Statement(s) (PTO-1449 or PTC ate <u>16</u> .		Paper No(s)/Mail D 5) Notice of Informal F 6) Other:		52)				

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 13-18, 64-67, 69, and 72-80 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pattillo et al. (USPN 4,937,194).

Pattillo et al. discloses an injection device with a first fluid source (10B), a second fluid source (142a or 138), a fluid path, and a mixing element (134, and the Y-connector [Column 8, lines 46-53]); as well as a metering device, a control unit, and a fluid assurance device. The "reusable portion" being the flow path from the mixing element down. The "disposable portion" being the fill bags (134a). (Figures 2, 5 and entire reference)

Claims 13-16, 64, 65, 66, 69, 72-75, 78, and 79 are rejected under 35
 U.S.C. 102(b) as being anticipated by Roberts (USPN 4,754,786).

Roberts discloses an injection device with a first fluid source, a second fluid source, a fluid path, and a mixing element; as well as a metering device, a control unit, and a fluid assurance device. The "reusable portion" being the flow path from the

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mixing element down. The "disposable portion" being the fill bags. (Figures 5, 6 and entire reference)

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 13-18, 63-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (USPN 4,710,166), and further in view of Wortich (USPN 4,750,643).

Thompson et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device (static and Y-connector), a pump or metering device, a control unit, valves and an electronic interface. (See Figures 1, and 11), but fails to disclose a fluid assurance device and multiple reusable and disposable portions.

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path.

(Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Thompson et al. with Wortich because Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients.

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6. Claims 13-18, 63-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orkin et al. (USPN 4,925,444).

Orkin et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device, a pump or metering device, a control unit, valves and an electronic interface, a fluid assurance element and one reusable portion and a disposable flow path, (Figure 1 and entire reference), but fails to discloses multiple reusable and disposable portions.

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path.

(Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Orkin et al. because Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients.

The examiner would also like to note that the multiplication of the infuse lines is a mere duplication of parts and has been indicated by the courts as taking only routine skill in the art, which would further support the 103 Rejections made above.

## Response to Arguments

7. Applicant's arguments with respect to claims 13-19 have been considered but are most in view of the new ground(s) of rejection.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763

April 19, 2004

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TECHNOLOGY CENTER 3700

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